807.87(h) 510(k) Summary

As required by Section 807.92(a)

FEB - 1 2010

(1) DATE OF PREPARATION: September 16, 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. FlexPen® *needle* meets all applicable product and quality standards.

SUBMITTER'S NAME AND ADDRESS:

Novo Nordisk Inc.
100 College Road West
Princeton, New Jersey 08540

Contact Person: Rick Spring
Tel: 609-987-5046
Fax: 609-987-3916

(2) NAME OF DEVICE:

Proprietary Name:	FlexPen® *needle*
Common or usual name:	Sterile disposable hypodermic needle
Classification:	Hypodermic single lumen needle (21 CFR 880.5570)
Class:	Class II

(3) SUBSTANTIAL EQUIVALENCE:

FlexPen® *needle* is a disposable needle which is substantially equivalent to K062500 cleared on November 21, 2006, NovoFine® 32G Tip (0.23/ 0.25 mm) x 6 mm disposable needle, cleared under 510(k) K053470, NovoFine® Autocover® 30G x 8 mm, cleared under 510(k) K050106, and to the Becton Dickinson BD Pen Needle (29G, 30G, 31G) x (5 mm, 8 mm, 12.7 mm), cleared under 510(k) K051899.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent laws or their application by the court.

(4) DEVICE DESCRIPTION:

FlexPen® *needle* is designed for single use in conjunction with Novo Nordisk injection delivery devices. Prior to giving an injection, the protective tab is removed from the outer needle cap of the single-use disposable needle. With the disposable needle remaining in the outer needle cap, it is then carefully screwed onto the injection delivery device until tight and then the needle outer and inner caps are removed. Prepare for injection by following the procedure described in the user manual provided with the pen injection device and instructions from your health care professional.

After the injection, the needle is removed from the skin. The needle is detached from the injection device and disposed of in accordance with national/local regulations. For each subsequent injection, another disposable needle must be used. Delivery device function checks can be performed with the FlexPen® *needle* by using the needle cap as described in the user manuals provided with the Novo Nordisk pen injection devices.

FlexPen® *needle* is used in exactly the same manner as the NovoFine® needles. The instructions for use are described in the user manuals for Novo Nordisk delivery devices for injection and are the same for all NovoFine® needles and FlexPen® *needle*.

(5) INTENDED USE:

FlexPen® *needle* is intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide, and somatropin.

(6) TECHNOLOGICAL CHARACTERISTICS:

FlexPen® *needle* is considered substantially equivalent to K062500, NovoFine® 32G Tip x 6 mm, NovoFine® Autocover® 30G x 8 mm, and to the Becton Dickinson BD Pen Needle (29G, 30G, 31G) in intended use (intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide and somatropin), technology/principle of operation, materials and performance. Differences between the devices do not raise any significant issues of safety and effectiveness.

As required by Section 807.92(b)

(1) NON-CLINICAL TESTS PERFORMED: None

FlexPen® *needle* will be manufactured in accordance with current Good Manufacturing Practices for Medical Devices. Biocompatibility and performance tests have been performed and the results are in compliance with existing domestic and international standards.

(2) CLINICAL TESTS SUBMITTED:

No clinical tests are required.

(3) CONCLUSIONS DRAWN FROM THE NON-CLINICAL AND CLINICAL TESTS:

Based on the design equivalency and the functional testing, Novo Nordisk had determined that FlexPen® *needle* is substantially equivalent to a device currently marketed in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.

Mary Ann McElligott

Mary Ann McElligott, Ph.D.
Associate Vice President, Regulatory Affairs
Novo Nordisk Inc.

18 Sept 09
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Rick Spring
Senior Manager, Regulatory Affairs
Novo Nordisk, Incorporated
100 College Road West
Princeton, New Jersey 08540

FEB - 1 2010

Re: K090111
Trade/Device Name: FlexPen Needle 32G Tip x 6mm (1/4") Disposable Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 26, 2010
Received: January 27, 2010

Dear Mr. Spring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K090111

Device Name: FlexPen *needle*
32G Tip x 6mm (1/4") Disposable Needle

Indications For Use: FlexPen® needles are intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide, and somatropin.

Prescription Use _____ AND/OR Over-The-Counter Use ____X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090111